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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,546	02/25/2002	Jean-Michel Lacroix	VGEN.P-054	4228
21121	7590	11/18/2003	EXAMINER	
OPPEDAHL AND LARSON LLP			HORLICK, KENNETH R	
P O BOX 5068			ART UNIT	
DILLON, CO 80435-5068			PAPER NUMBER	
			1637	7

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,546

Applicant(s)

LACROIX, JEAN-MICHEL

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 is/are allowed.
- 6) ☒ Claim(s) 14-18 is/are rejected.
- 7) ☒ Claim(s) 10-13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 (4 pages) 6) ☐ Other: ____

1. Claims 10-13 are objected to because of the following informality: an inappropriate period appears in line 2 of claim 10. Correction is required.
2. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A) Claims 14-18 are confusing because of the language "with the first sequencing" at the end of claim 14 – a word appears to be missing. Correction is required.
 - B) Claim 16 is further confusing because "the first and second regions" lacks proper antecedent basis in claim 14 (dependency from claim 15 is apparently intended).
 - C) Claim 17 is further confusing because of the language "an insertion of deletion mutation". Correction is required.
 - D) Claim 18 is further confusing because of the language "and the first and region is". Correction is required.

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3. Claims 1-9 are allowable. Claims 10-18 are free of the prior art, but are objected to or rejected for other reasons. Claims 10-13 require an internal quantitation standard derived from an analyte nucleic acid by incorporation of a plurality of sequence variations, including a first variation which renders amplification products formed from the standard distinguishable from amplification products formed from the analyte, and a second variation effective to substantially eliminate the production of sequencing products from the interaction of the standard with a sequencing primer, said sequencing primer being effective for producing sequencing fragments from amplified analyte.

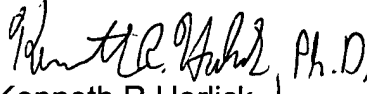
Claims 1-9 and 14-18 are drawn to methods and kits, respectively, which require such an internal quantitation standard. While the prior art teaches internal standards for quantitative PCR amplification wherein the standard is modified from the target analyte such that amplification products generated from the two are distinguishable (see, for example, Jordan US 6,017,699), the prior art does not teach or suggest a second modification in such a standard to substantially eliminate the production of sequencing products from the interaction of the standard with a sequencing primer, said sequencing primer being effective for producing sequencing fragments from amplified analyte.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
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11/13/03